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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,373	09/01/2000	Sean C Semple	INEX.P-007	5857

21121 7590 01/28/2003
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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/65433

Applicant(s)

Sample et al

Examiner

H. J. J.

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/29/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.
- Of the above claim(s) 10-22 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-9 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The amendment of 10/28/02 amended the specification and claim 1.

Claims 10-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in
5 Paper No. 8 (filed 1/10/02).

Claims examined on the merits are 1-9 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10 ***Claim Rejections - 35 USC § 112***

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by "steric barrier lipid" in
15 (a) of claim 1 being uncertain as to meaning and scope.

Response to Arguments

Applicants assert that the examiner did not state why the term is indefinite. However, the examiner stated that the term is uncertain as to meaning and scope. The specification does not define the term as
20 being a structural barrier that physically blocks molecular interactions. The term "steric" has to do with the arrangement of atoms in space as defined in the dictionary, and is not defined as a material that provides a structural barrier that physically blocks. If the term "steric barrier" has an art recognized definition as being a structural barrier
25 that physically blocks molecular interactions, it is suggested that a

copy of a publication using and defining the term be provided. The specification (paragraph bridging pages 10 and 11) defines the steric barrier lipid only in terms of materials that are a steric barrier lipid and not how the steric barrier lipid functions.

5 ***Claim Rejections - 35 USC § 103***

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler et al (WO 96/40964).

The claims are drawn to oligodeoxynucleotide-containing lipid vesicles in an aqueous carrier wherein a portion of the vesicles are
10 multilamellar vesicles containing 20-30% ionizable amino lipid, a steric barrier lipid and neutral or sterols, and oligodeoxynucleotides in the lumen or interlamellar spaces of the multilamellar vesicles.

Wheeler et al disclose encapsulating a therapeutic agent such as antisense oligonucleotides or ribozymes (page 17, lines 14-15) in a lipid
15 bilayer (page 23, lines 3-15, and page 26, line 23) prepared from cationic and non-cationic lipids (page 4, lines 2-7, and page 26, line 17) to provide lipid particles of about 50-150 nm in size containing encapsulated nucleic acid. The cationic lipid is an amino lipid (page 15, line 16) and the non-cationic lipid may be polyethylene glycol
20 conjugated to ceramides such as PEG-CerC14 (page 25, lines 17-20, and Table 1 (page 53) and Table 2 (page 54)). As shown in the tables, lipid mixtures containing an amino lipid, a mixture of neutral lipids and a PEG-ceramide are used to encapsulate nucleic acids. The lipid encapsulated nucleic acid can be used to treat a patient by gene therapy
25 to suppress gene expression (paragraph bridging pages 42 and 43).

The lipid particles containing encapsulated nucleic acids of Wheeler et al can be multilamellar, have the same composition and inherently have oligodeoxynucleotides as presently claimed. It would have been obvious to put the particles in an aqueous carrier for therapeutic use.

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Response to Arguments

Applicants urge that the cationic lipid of Wheeler et al is not an ionizable lipid. However, a cationic lipid that can be used by Wheeler et al is DOGS (page 15, line 16). This lipid is also disclosed in the present specification (page 10, line 24) as being an ionizable lipid that
10 can be used. Thus, it is clear that Wheeler et al is not limited to quaternary amines, and that Wheeler et al intend the cationic lipid to include ionizable lipids. Selecting known ionizable lipids other than DOGS would have been merely a matter of individual preference.

Double Patenting

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Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 6,287,591 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed composition would have been obvious from the claims of
20 the patent drawn to nucleic acid-containing vesicles.

Response to Arguments

Applicants indicate that a terminal disclaimer will be filed when allowable claims are determined.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension
25 of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the
5 end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing
10 date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00
15 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number
20 (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN
1/27/03


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 12857